K134021

JUN 10 2014

SPIDENT Co., Ltd.
203&312, Korea Industrial Complex, 722, Gojan-Dong,
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: November 22, 2013

1. Company and Correspondent making the submission:

	Company
Name	SPIDENT Co., Ltd.
Address	203&312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea 405-821
Phone Fax	+82(32)819-4571 +82(32)819-4572
Contact	Jemo Ahn

2. Device:
   Proprietary Name – EsTemp Implant, EsTemp Clear
   Common Name – Dental Cement
   Classification Name – Cement, Dental

3. Predicate Device:
   Premier Implant Cement, K033309

4. Classifications Names & Citations:
   EMA, 872.3275

5. Description:
   Estemp temporary resin cement series consists of EsTemp Implant & EsTemp Clear. Each is designed to be suitable for various applications such as cementing temporary crowns, bridges, inlays, onlays and splints. They are available in an automix dual barrel syringe. It is light-curing temporary filling materials

   The EsTemp Implant, EsTemp Clear is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. They are substantially equivalent in design, function and intended use to the predicate devices.

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6. Indication for use:

EsTemp Implant, EsTemp Clear is a non-eugenol temporary cement for luting implant-retained crowns, bridges, inlays, onlay and splints.

7. Performance

Testing performed including Chemistry of the setting reaction, Proportion of powder to liquid, Maximum solubility and disintegration, Dimensional Change, Working and setting Time, Bonding Strength, Optimum Film thickness, Conductivity & Amount of heat generated during setting, Compressive Strength use which demonstrated that the EsTemp Implant, EsTemp Clear is equivalent to the predicates in specifications and performance characteristics.

Therefore, it was considered that the subject device was as effective as and performs as good as the predicate device.

In conclusion, it can be said that the effectiveness and performance of the subject device are substantially equivalent to those of the predicate device.

8. Biocompatibility

Biocompatibility testing confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum #95-1 entitled Use of International Standards ISO 10993 Biological Evaluation of Medical Devices Part -1: Evaluation and Testing, and is biocompatible. Accordingly, it was considered that the subject device was substantially equivalent in safety to the predicate device.

No.	Testing Biocompatibility	Results
1	Cytotoxicity	Pass
2	Sensitization	Pass
3	Irritation or Intracutaneous reactivity	Pass
4	Subacute toxicity	Pass
5	Genotoxocity	Pass

9. Review:

EsTemp Implant, EsTemp Clear is the similar device characteristics as the predicate device, the Premier Implant Cement; intended use, material, chemical composition, design and use concept are similar.

EsTemp Implant, EsTemp Clear have the similar mechanical properties as the predicate device; Dimensional Change, Working and setting Time, Solubility, Film thickness and Compressive Strength.

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EsTemp Implant, EsTemp Clear has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the US regulations and ISO 4049.

Based on the comparison of intended use and technical features, the EsTemp Implant, EsTemp Clear is substantially equivalent to the predicate devices.

10. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance for the Preparation of Premarket notifications for Dental Composite" and based on the information provided in this premarket notification SPIDENT Co., Ltd. concludes that the EsTemp Implant, EsTemp Clear is safe and effective and substantially equivalent to predicate devices as described herein.

11. SPIDENT Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

SPIDENT Company, Limited.
c/o Ms. Lena Pak
SPIDENT, USA, Incorporated
2115 Linwood Avenue, 5th Floor
Fort Lee, NJ 07024

Re: K134021
Trade/Device Name: EsTemp Implant, EsTemp Clear
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: 872.3275
Product Code: EMA
Dated: March 5, 2014
Received: March 7, 2014

Dear Ms. Pak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Brunner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 134021

Device Name: EsTemp Implant, EsTemp Clear

Indication for use:
EsTemp Implant, EsTemp Clear is a non-eugenol temporary cement for luting implant-retained crowns, bridges, inlays, onlay and splints.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A Green -S
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